

We claim:

1. A oral polymeric controlled release formulation suitable for once-a-day administration comprising:
  - a) divalproex sodium;
  - 5 b) said divalproex sodium is in association with a sufficient quantity of a pharmaceutically acceptable polymer, and;
  - c) when said formulation is ingested orally, said formulation produces a  $C_{\max}$  that is statistically significantly lower than the  $C_{\max}$  produced by a delayed release divalproex sodium tablet, when each is determined at  
10 steady state in a healthy fasting population.
2. The formulation according to claim 1 which produces a  $C_{\min}$  that is not statistically significantly different from the  $C_{\min}$  produced by said delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population.
- 15 3. The formulation according to claim 1 in which said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each is determined at steady state in a healthy fasting population.
4. The formulation according to claim 1 which:
  - 20 a) produces a  $C_{\min}$  that is not statistically significantly different from the  $C_{\min}$  produced by said delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population, and;
  - b) said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when  
25 each is determined at steady state in a healthy fasting population.
5. The formulation according to claim 4 which produces a DFL that is lower than the DFL produced said delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population.
6. The formulation according to claim 1 in which said formulation is a  
30 matrix system, an osmotic pump system or a reservoir polymeric system.

7. A oral polymeric controlled release formulation suitable for once-a-day administration comprising:

- a) divalproex sodium;
- b) said divalproex sodium is in association with a pharmaceutically acceptable polymer, and;
- c) when said formulation is ingested orally said formulation produces:
  - i. a  $C_{\max}$  that is statistically significantly lower than the  $C_{\max}$  produced by a delayed release divalproex sodium tablet, when each  $C_{\max}$  is determined at steady state in a healthy fasting population,
  - ii. a  $C_{\min}$  that is not statistically significantly different from the  $C_{\min}$  produced by said delayed release divalproex sodium tablet, when each  $C_{\min}$  is determined at steady state in a healthy fasting population, and;
  - iii. said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each AUC is determined at steady state in a healthy fasting population.

8. The formulation according to claim 7 in which said formulation produces steady state peak plasma valproate levels that are about 10 to about 20% lower than that produced by a said delayed release divalproex sodium tablet.

9. A method for the treatment of migraine comprising the administration of a formulation according to claim 1 to a patient in need thereof.

10. A method for the treatment of epilepsy comprising the administration of a formulation according to claim 1 to a patient in need thereof.

11. A method for the treatment of mania associated with a bipolar disorder comprising the administration of a formulation according to claim 1 to a patient in need thereof.

12. A method for the reduction of side effects associated with divalproex sodium therapy comprising the administration of a formulation according to claim 1.

13. A oral polymeric controlled release formulation suitable for once-a-day administration comprising:

- a) a valproate compound;
- b) said valproate compound is in association with a sufficient quantity of a pharmaceutically acceptable polymer, and;
- c) when said formulation is ingested orally, said formulation produces a  $C_{max}$  that is statistically significantly lower than the  $C_{max}$  produced by a bid dosage form of said valproate compound, when each is determined at steady state in a healthy fasting population.

14. The formulation according to claim 13 which produces a  $C_{min}$  that is not statistically significantly different from the  $C_{min}$  produced by said bid dosage form when each is determined at steady state in a healthy fasting population.

15. The formulation according to claim 13 in which said formulation produces an AUC value that is equivalent to the AUC value generated by said bid valproate dosage form, when each is determined at steady state in a healthy fasting population.

16. The formulation according to claim 13 which:

- a) produces a  $C_{min}$  that is not statistically significantly different from the  $C_{min}$  produced by said bid valproate dosage form, when each is determined at steady state in a healthy fasting population, and;
- b) said formulation produces an AUC value that is equivalent to the AUC value generated by said bid valproate dosage form, when each is determined at steady state in a healthy fasting population.

17. The formulation according to claim 13 which produces a DFL that is not statistically significantly different than the DFL by produced said bid valproate dosage form, when each is determined at steady state in a healthy fasting population.

18. The formulation according to claim 13 in which said formulation is a matrix system, an osmotic pump system or a reservoir polymeric system.

19. An oral matrix formulation suitable for once-a-day administration comprising:

- a) from about 40 to about 80 w/w% of divalproex sodium;
- b) a sufficient quantity of a pharmaceutically acceptable polymer, and;
- c) when said formulation is ingested orally:
  - i. said formulation produces a  $C_{\max}$  that is statistically significantly lower than the  $C_{\max}$  produced by a delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population,
  - ii. a  $C_{\min}$  that is not statistically significantly different from the  $C_{\min}$  produced by said delayed release divalproex sodium tablet, when each  $C_{\min}$  is determined at steady state in a healthy fasting population, and;
  - iii. said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each AUC is determined at steady state in a healthy fasting population.

20. A oral osmotic pump formulation suitable for once-a-day administration comprising:

- a) divalproex sodium;
- b) said divalproex sodium is in association with a sufficient quantity of a pharmaceutically acceptable semipermeable polymer, and;
- c) when said formulation is ingested orally:
  - i. said formulation produces a  $C_{\max}$  that is statistically significantly lower than the  $C_{\max}$  produced by a delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population,
  - ii. a  $C_{\min}$  that is not statistically significantly different from the  $C_{\min}$  produced by said delayed release divalproex sodium tablet, when

each  $C_{min}$  is determined at steady state in a healthy fasting population, and;

- iii. said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each AUC is determined at steady state in a healthy fasting population.

21. A reservoir polymeric formulation suitable for once-a-day administration comprising:

- a) divalproex sodium;
- b) said divalproex sodium is in association with a sufficient quantity of a pharmaceutically acceptable polymer, and;
- c) when said formulation is ingested orally:
- i. said formulation produces a  $C_{max}$  that is statistically significantly lower than the  $C_{max}$  produced by a delayed release divalproex sodium tablet, when each is determined at steady state in a healthy fasting population,
- ii. a  $C_{min}$  that is not statistically significantly different from the  $C_{min}$  produced by said delayed release divalproex sodium tablet, when each  $C_{min}$  is determined at steady state in a healthy fasting population, and;
- iii. said formulation produces an AUC value that is equivalent to the AUC value generated by said divalproex sodium delayed release tablet, when each AUC is determined at steady state in a fasting population.